ATTACHMENT 43

TCI AJW TECHNOLOGY CONSULTANTS, INC.

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Date: December 17, 2015

Document Mail Center (W066-06)
Center For Devices and Radiological Health
Food and Drug Administration
10903 New Hampshire Ave
Silver Spring, MD 20993

Re: K143619

Dear Dr. Wen:

Please allow this letter to serve a notice of our client's (Rebotix, LLC) intent to withdraw the above mentioned 510(k) Premarket Notification. We will require additional time in order to address the requests for additional information dated June 23, 2015. Due to the nature of the testing and information requested we will not be able to respond within the 180 day allotted timeframe. It is our intent to resubmit the 510(k) at a later date once the data has been collected and compiled.

Thank you for your time and consideration.

Best regards,

Ryan Burke
Regulatory Correspondent (K143619)